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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,783	02/20/2004	Alan R. Klenk	MVMDINC.060A	6668

20995 7590 11/30/2009

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EXAMINER	
YABUT, DIANE D	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
11/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/783,783	KLENK ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-25 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-25 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 07/27/2009.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 07/27/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-15, 17-25, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chanduszko et al.** (U.S. Pub. No. **2005/0059984**) in view of **Johnson et al.** (U.S. Patent No. **6,485,504**).

Chanduszko et al. disclose a method comprising delivering an elongate body **104** through an outer catheter **102**, the elongate body having a proximal end and a distal end to the patent foramen ovale, the elongate body having a tissue piercing structure **134** at its distal end and an anchor or "suture device" **108**, advancing the tissue piercing structure and the anchor through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the anchor extend into the septum secundum **62** and

the septum primum **60**, and releasing the anchor from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the anchor, when released, pinches the septum primum and the septum secundum together (Figures 12A-12D; paragraphs 43 and 74-81). The elongate body has an opening **132** near its distal end, and a loading portion or collar **106** releasably engages a proximal end **142** of the anchor after the anchor is advanced through the patent foramen ovale. The elongate body and the loading collar are axially slideable relative to one another. The elongate body is advanced to pierce the septa prior to advancing the anchor axially to position the anchor. The tissue piercing structure is retracted from the septum primum and the septum secundum after releasing the anchor from the delivery device.

Chanduszko et al. disclose the claimed invention except for the anchor being a coil having a distal end that releasably engages the opening in the elongate body near its distal end and axially elongating and radially reducing the coil by moving and rotating the piecing structure distal end relative to the loading collar, wherein the coil axially contracts to pinch the septum primum and the septum secundum together.

Johnson et al. teach a method of closure for hard or soft tissue including a coil ("grommet") **100** having a distal end or tang **110** that is releasably engaged with an opening **116** on the distal end of elongate body **108**, and advancing and rotating the distal end of the coil with the elongate body in order to axially elongate and radially reduce the coil, and then retracting the elongate body from the tissue to allow the distal end of the coil to exit the opening of the elongate body and to be disengaged from the

elongate body (Figures 24-26). Additional coils may also be inserted into other portions of the tissue as seen in Figures 24-25. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Chanduszko et al. by having coil anchors with a distal end of the coil being releasably engaged to the distal end of the elongate body, as taught by Johnson et al., in order to effectively narrow the coil in diameter to facilitate deployment through tissue and also to minimize damage to tissue and allow flexibility and movement with the coil anchor without disturbing the healing process (col. 1, lines 32-36 and col. 19, lines 9-32).

Although a plurality of coils sequentially positioned on the loading portion is not expressly disclosed by either Chanduszko et al. or Johnson et al., it would have been obvious of one of ordinary skill in the art to modify the loading portion of Chanduszko et al. to accommodate multiple anchors or coils in order to further secure the septum primum and septum secundum together.

3. Claims 27 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chanduszko et al.** (U.S. Pub. No. **2005/0059984**) in view of **Johnson** (U.S. Patent No. **6,485,504**), as applied to claims 20 and 31 above, and further in view of **Kay** (U.S. Patent No. **5,662,683**).

Chanduszko et al. and Johnson et al. disclose the claimed invention except for the proximal end of the coil which having a tang that extends into a diameter defined by the coil and rotating the loading collar to allow the proximal end of the coil to disengage from the loading collar.

Kay teaches a coil anchor **12** having a proximal end with a tang **17** that extends into a diameter defined by the coil and is releasably engaged to a loading collar **30**, wherein rotating the loading collar allows the proximal end of the coil to disengage from the loading collar (Figure 7. col. 4, lines 49-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tang on the coil which is releasably engaged to a loading collar by rotation, as taught by Kay, to the combined invention of Chanduszko et al. and Johnson et al. in order to facilitate attachment and detachment from the coil by just applying torque to the loading collar.

Response to Arguments

4. Applicant's arguments filed 07/27/2009 have been fully considered but they are not persuasive.

5. Applicant generally argues that modifying Chanduszko with Johnson would be improper since one would not dispose the coil of Johnson on the outside of the elongate member 104 of Chanduszko, which would render the device inoperable. However, the modification is not meant to alter the position of Chanduszko's releasably engageable proximal end 142 of anchor 108 to a loading portion 106, which is disposed inside of the elongate member 104 (Figures 12A-12D). The teaching of Johnson is directed to the releasably engaged distal end of a coil anchor 100 to an elongate member 108, while the coil anchor's proximal end is held relative to its distal end. The teaching suggests a method of introducing an effective coil anchor that narrows during deployment and

minimizes damage to tissue and allows flexibility and movement disturbing the healing process. Therefore, the suggestion is not to dispose the coil anchor of Johnson around the elongate member 104 of Chanduszko, but rather to maintain the position of the anchor within the elongate member 104 anchor with a proximal end that would remain releasably coupled to the loading portion 106. The modification would involve modifying the I-shaped anchor 108 into a coil anchor with a distal end that would be coupled to a slot in the distal end of elongate member 104 instead of having a free distal end, as taught by Johnson.

6. In response to applicant's argument that Chanduszko and Johnson are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references address the particular problem of introducing anchors or closure devices into tissue holes of the body.

7. Applicant also argues that engaging both ends of the anchor defeats the purpose and functionality of the respective devices and methods of Chanduszko and Johnson, and therefore one skilled in the art would not arrive at such a combination. However, modifying the method and device of Chanduszko with Johnson would not defeat the purpose of deploying an anchor through septal tissue. To have both ends of an anchor be releasably engaged to the delivery device rather than just one suggests a more controlled positioning and release of the anchor within tissue, as taught by Johnson.

8. Lastly, applicant argues that there is no suggestion in the prior art to use a plurality of coils rather than just one coil on a single delivery device, and how the combined invention of Chanduszko and Johnson would incorporate multiple coils and load them by retracting the tissue piercing structure proximally to engage an additional coil without removing the tissue piercing structure from the body of the patient. Although a plurality of coils sequentially positioned on the loading portion is not expressly disclosed by either Chanduszko et al. or Johnson et al., it would have been obvious of one of ordinary skill in the art to modify the loading portion of Chanduszko et al. to accommodate multiple anchors or coils in order to further secure the septum primum and septum secundum together. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/23/09